(a) Satisfies the general requirements specified in § 30.33 of this chapter;

(b) Provides a description of the product or material into which the byproduct material will be introduced, intended use of the byproduct material and the product or material into which it is introduced, method of introduction, initial concentration of the byproduct material in the product or material, control methods to assure that no more than the specified concentration is introduced into the product or material, estimated time interval between introduction and transfer of the product or material, and estimated concentration of the radioisotopes in the product or material at the time of transfer; and

(c) Provides reasonable assurance that the concentrations of byproduct material at the time of transfer will not exceed the concentrations in § 30.70 of this chapter, that reconcentration of the byproduct material in concentrations exceeding those in § 30.70 is not likely, that use of lower concentrations is not feasible, and that the product or material is not likely to be incorporated in any food, beverage, cosmetic, drug or other commodity or product designed for ingestion or inhalation by, or application to, a human being.

[30 FR 8192, June 26, 1965, as amended at 49 FR 19625, May 9, 1984]

§ 32.12 Same: Records and material transfer reports.

(a) Each person licensed under § 32.11 shall maintain records of transfer of material and file a report with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, with a copy to the appropriate NRC Regional Office listed in appendix D of part 20 of this chapter.

(b) The report must identify the:

(1) Type and quantity of each product or material into which byproduct material has been introduced during the reporting period;

(2) Name and address of the person who owned or possessed the product or material, into which byproduct material has been introduced, at the time of introduction;

(3) The type and quantity of radionuclide introduced into each product or material; and

(4) The initial concentrations of the radionuclide in the product or material at time of transfer of the byproduct material by the licensee.

(c) The licensee shall file the report within 30 days following:

(1) Five years after filing the preceding report; or

(2) Filing an application for renewal of the license under § 30.37; or

(3) Notifying the Commission under § 30.34(f) of the licensee's decision to permanently discontinue activities authorized under the license issued under § 32.11.

(d) The report must cover the period between the filing of the preceding report and the occurrence specified in paragraphs (c) (1), (2), or (3) of this section. If no transfers of byproduct material have been made under § 32.11 during the reporting period, the report shall so indicate.

(e) The licensee shall maintain the record of a transfer for a period of one year after the event is included in a report to the Commission.

[48 FR 12333, Mar. 24, 1983; 48 FR 14863, Apr. 6, 1983]

§ 32.13 Same: Prohibition of introduction.

No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under § 30.14 of this chapter or equivalent regulations of an Agreement State, except in accordance with a license issued pursuant to § 32.11 or the general license provided in § 150.20 of this chapter.

[30 FR 8192, June 26, 1965]

§ 32.14 Certain items containing byproduct material; requirements for license to apply or initially transfer.

An application for a specific license to apply byproduct material to, or to incorporate byproduct material into, the products specified in § 30.15 of this chapter or to initially transfer for sale or distribution such products containing byproduct material for use pursuant to § 30.15 of this chapter will be approved if:

(a) The applicant satisfies the general requirements specified in §30.33 of this chapter;

(b) The applicant submits sufficient information regarding the product pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of byproduct material in each product;

(2) Details of construction and design of each product;

(3) The method of containment or binding of the byproduct material in the product;

(4) Procedures for and results of prototype testing to demonstrate that the material will not become detached from the product and that the byproduct material will not be released to the environment under the most severe conditions likely to be encountered in normal use of the product;

(5) Quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet;

(6) The proposed method of labeling or marking each unit, except timepieces or hands or dials containing tritium or promethium-147, and its container with the identification of the manufacturer or initial transferor of the product and the byproduct material in the product;

(7) For products for which limits on levels of radiation are specified in §30.15 of this chapter, the radiation level and the method of measurement;

(8) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the product.

(c) Each product will contain no more than the quantity of byproduct material specified for that product in §30.15 of this chapter. The levels of radiation from each product containing byproduct material will not exceed the limits specified for that product in §30.15 of this chapter.

(d) The Commission determines that:

(1) The byproduct material is properly contained in the product under the most severe conditions that are likely to be encountered in normal use and handling.

(2) For automobile lock illuminators, the product has been subjected to and meets the requirements of the prototype tests prescribed by §32.40, schedule A.

[31 FR 5316, Apr. 2, 1966, as amended at 34 FR 6652, Apr. 18, 1969; 43 FR 6922, Feb. 17, 1978; 63 FR 32971, June 17, 1998]

§32.15 Same: Quality assurance, prohibition of transfer, and labeling.

(a) Each person licensed under §32.14 shall:

(1) Maintain quality assurance practices in the manufacture of the part or product, or the installation of the part into the product;

(2) Subject inspection lots to such testing as may be required as a condition of the license issued under §32.14 taking a random sample of the size required by the tables in §32.110, and for Lot Tolerance Percent Defective of 5.0 percent, accept or reject inspection lots in accordance with the directions of §32.110; and

(3) Visually inspect each unit, except electron tubes containing byproduct material, in inspection lots. Any unit which has an observable physical defect that could affect containment of the byproduct material shall be considered as a defective unit.

(b) An application for a license or for amendment of a license may include a description of procedures proposed as alternatives to those prescribed by paragraph (a)(2) of this section, and proposed criteria for acceptance under those procedures. The Commission will approve the proposed alternative procedures if the applicant demonstrates that the operating characteristic curve or confidence interval estimate for the alternative procedures provides a Lot Tolerance Percent Defective of 5.0 percent at the consumer's risk of 0.10.

(c) No person licensed under §32.14 shall transfer to other persons for use under §30.15 of this chapter or equivalent regulations of an Agreement State:

(1) Any part or product which has been tested and found defective under the criteria and procedures specified in the license issued under §32.14, unless the defective units have been repaired or reworked and have then met such